Ambient AI for Reducing Nursing Staff Documentation Time
NCT07456241

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UNIVERSITY OF WISCONSIN – MADISON
Research Participant Information Sheet

Title of the Study: Ambient AI for Reducing Nursing Staff Documentation Time

Principal Investigators: Ann Wieben, PhD, RN, NI-BC and Jann Pfaff, PhD, RN, GCNS-BC. Dr. Wieben's phone number at the University of Wisconsin – Madison is 608-265-1029 and email address is wieben@wisc.edu. Dr. Pfaff's email address is jpfaff2@uwhealth.org.

DESCRIPTION OF THE RESEARCH

You are invited to participate in a research project about whether Artificial Intelligence-Driven Ambient Listening software may impact the time you spend documenting in the electronic health record (EHR). You have been selected as a potential participant because you are a Registered Nurse or Nursing Assistant in the UW Health East Madison Hospital and Ambient Listening is being implemented in your department.

WHAT WILL MY PARTICIPATION INVOLVE?

This study is divided into three periods: a baseline period, a study treatment period, and a final follow-up period. In each period, you will be asked to complete online surveys that should take about 5 minutes to complete. We will use REDCap, a secure web-based survey system approved for research studies, to collect your responses. You will be asked questions about your level of well-being related to EHR documentation, your thoughts on the usefulness and experience with the AI tool. You can choose not to answer any of the questions you are asked.

Study participation may last up to 22 weeks. In addition to the surveys, documentation metrics such as time spent documenting in flowsheets and documentation completed after the end of your shift will be collected. These data will be retrieved from the electronic health record and software used.

You may also be asked if you would like to participate in optional interviews. The interviews would be approximately 20 minutes long and would occur via a HIPPA approved virtual platform (i.e. Cisco Webex).

Audio recordings will be made of the interview. Only the researchers will have access to these recordings. The researchers or someone hired by the researchers will listen to the recording and write down what people said during the interview. The written copy is called a transcription. The transcription will be saved but the recording will be destroyed. No information that could identify you will be included in the transcription.

Participation is voluntary. You can stop participating at any time. Refusal to participate or discontinuation of participation will involve no penalty or loss of benefits to which you are otherwise entitled.

ARE THERE ANY RISKS TO ME?

You may find discomfort while adapting to a new documentation system. You will be provided with comprehensive training and ongoing support to alleviate this. Although the research team will make every effort to keep your answers confidential, there is a small risk for that confidentiality to be breached. See “How Will My Confidentiality be Protected” to learn about how researchers will protect confidentiality.

ARE THERE ANY BENEFITS TO ME?

There are no direct benefits to participants. The only potential benefit to participants is knowing they are contributing to generalizable knowledge related to this technology.

WILL I BE COMPENSATED FOR MY PARTICIPATION?

You will not receive direct financial compensation for completing the research study surveys. If you agree to participate in the optional interviews, you will receive $10 per interview to compensate you for your time. You may end your participation at any time.

HOW WILL MY CONFIDENTIALITY BE PROTECTED?

We have strict rules to protect your personal information. We will limit the use and disclosure of your personal information, including research study records, as described in this consent form.

However, we cannot promise complete confidentiality. We will share information with individuals or organizations identified in this consent form. Federal or state laws may also permit or require us to show information to university or government officials responsible for carrying out or monitoring this study. This includes University of Wisconsin and its representatives and affiliates, including those responsible for ensuring compliance, such as the Human Research Protection Program.

While there may be publications as a result of this study, your name or any identifiable information will not be used.

All the documentation metric data will be collected in a secure application, stored secure UW–Madison and UW Health servers and devices, and will never be released to third parties without prior written approval.

A description of this clinical trial is available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results.

WILL MY DATA BE USED IN OTHER RESEARCH?

With appropriate confidentiality protections, we might use information that we collect during this study for other research, or share it with other researchers without additional consent from you.

We may share interview summaries and survey responses in our public resource website without cost. The de-identified survey data and interview summaries may be shared publicly so other researchers can repeat the study or use the data for future research.

We will remove direct identifiers about you, such as your name and other information we think could be used to identify you. However, we cannot guarantee there is no risk you could be identified. Information in free text fields such as those in transcripts of interviews and survey responses may contain details that could be used with other available information to identify you (such as an employer name or job title).

The study team will email you during the course of the study. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the study investigators using the contact information below.

If you have questions, concerns or complaints about the research, please contact the Principal Investigators Ann Wieben, PhD, RN, NI-BC and Jann Pfaff, PhD, RN, GCNS-BC. Dr. Wieben's phone number at the University of Wisconsin – Madison is 608-265-1029 and email address is wieben@wisc.edu. Dr. Pfaff's email address is jpfaff2@uwhealth.org.

If you have concerns about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. UW Staff not part of the study team will work with you to address concerns and assist in resolving any complaints.